## REMARKS

In the Office Action, Claims 27-34 and 78-91 were rejected over the prior art as discussed below. In this Amendment, Claim 27 has been amended and Claims 92-103 have been added. No claims have been canceled. Therefore, Claims 27-34 and 78-103 remain pending for further consideration.

***Discussion of One Non-Limiting Embodiment***

The specification describes a catheter 18 for repairing a heart valve suffering from valvular regurgitation. The repair can be performed while the heart is beating. The catheter 18 has a procedure zone (including leaflet immobilization supports 22, 23) and a distal portion that comprises an anchor zone AZ, as illustrated in Figure 9.

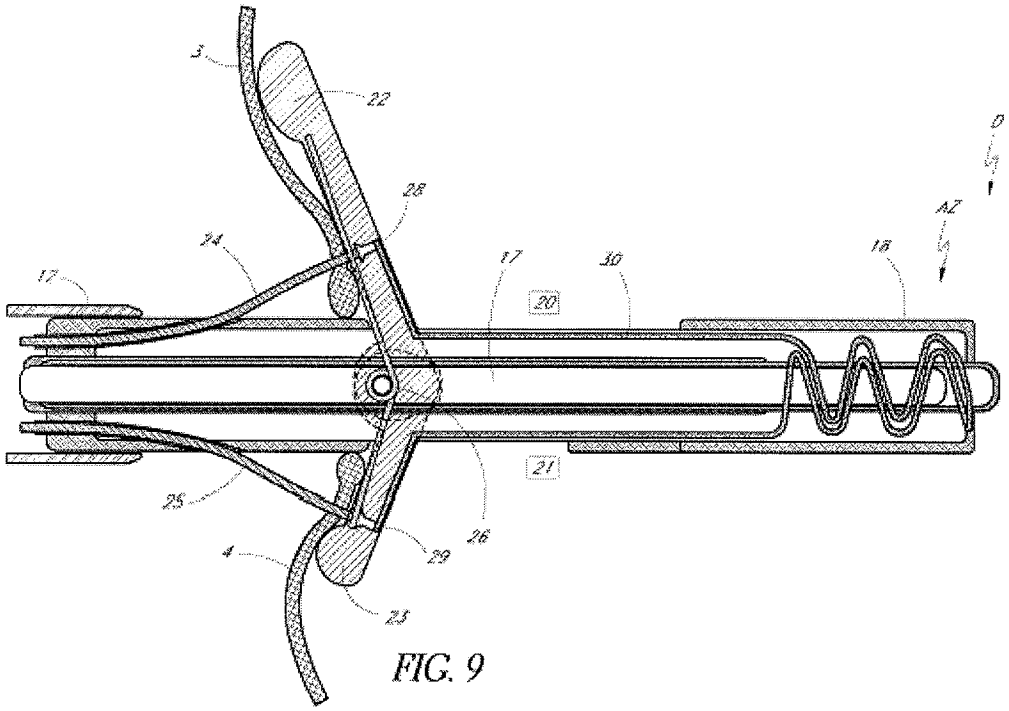


*FIG. 9*

The catheter 18 orients leaflet immobilization supports 22, 23, which, as illustrated above, are asymmetric in some embodiments to interact optimally with the asymmetric configuration of the mitral valve. The catheter 18 is advantageous in that it permits the supports 22, 23 to be positioned to capture the center of the anterior mitral valve leaflet and the center scallop of the three scallops of the posterior mitral valve leaflet if used to repair a mitral valve. The catheter 18 also avoids entanglement with chordae tendinae, which extend across the left ventricle interconnecting the

mitral valve leaflets and the papillary muscles, as the catheter traverses the left ventricle. A curled distal tip as in Cribier (discussed below) is useless for this purpose and would in fact become entangled in the chordae.

The catheter 18 traverses a tight curve that includes a bend of more than 90 degrees, e.g., about 120 degrees, in passing through the mitral valve into the left ventricle and thereafter into and in some cases through the left ventricular outflow tract into the aorta. This tight curve is illustrated in Figure 3 in connection with an orientation catheter 11 that is used in some techniques, and which traverses the same bend traversed by the catheter 18. This positioning provides a good angle of approach for the catheter 18 to grasp the posterior leaflet of the mitral valve, which can be difficult to catch, if the catheter is used in a mitral valve repair.

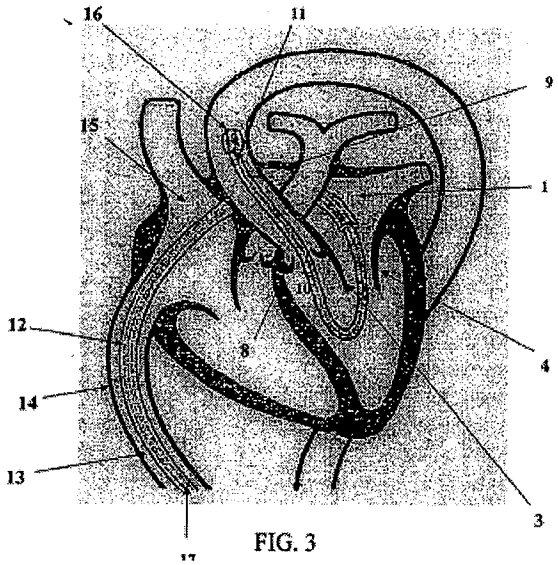


FIG. 3

After delivery through the mitral valve and into the left ventricle, the anchor zone AZ engages the left ventricular outflow tract and/or a wall of the aorta. This engagement with the left ventricular outflow tract or aorta and the tightly curved configuration of the catheter 18 after traversing path provide a fulcrum about which the catheter can be manipulated to orient and position the procedure zone. This fulcrum provides the operator with sufficient leverage to manipulate the procedure zone in a plurality of directions and degrees of freedom such that the leaflet immobilization supports 22, 23 can be positioned and oriented adjacent to the corresponding leaflets 3, 4. As a result, mitral valve 3, 4 of a beating heart can be captured and a procedure to address valvular regurgitation can be performed through the valve.

Rejections Under 35 U.S.C. § 112

Claims 27-34 and 78-91 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner states that "[t]he original disclosure does not disclose wherein the anchor zone is configured to bend at least about 90 degrees, in the specification, the drawings or the claims." Office Action, page 2. Applicants respectfully disagree.

In order to satisfy a § 112 written description requirement, the applicant must show "with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Possession of the claimed invention may be shown by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See M.P.E.P., § 2163, p. 166; see Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997).

Paragraph [0045] of the specification as published and Figure 3 describe the tortuous path that the orientation catheter 11 takes if delivered via the inferior vena cava 14 to the ascending aorta 9. From the inferior vena cava 14, the orientation catheter 11 proceeds in one described technique into the right atrium 15, trans-septally into the left atrium 1, then between the anterior leaflet 3 and posterior leaflet 4 leaflet of the mitral valve into the ventricle. As discussed above, the catheter 11 the traverses a tight curve to proceed into the left ventricular outflow tract 10, and through the aortic valve 8 into the ascending aorta 9.

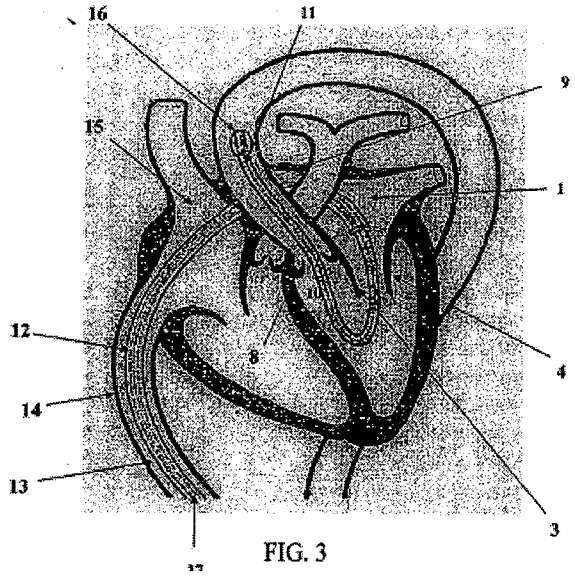


FIG. 3

As shown in Figure 3, the orientation catheter 11 bends more than 90 degrees as the catheter passes through a tight curve from the left atrium 1 through the left ventricular outflow tract 10 and into the ascending aorta 9. Also, the Specification notes that "[i]n one embodiment, the orientation catheter once in place in the ascending aorta may be removed over a guide wire and the device Housing Catheter 18 advanced over the wire until its distal end is in the ascending aorta." Specification at ¶ [0049]. The foregoing illustrates that the anchor zone AZ of the distal portion of the catheter 18 can traverse the same path as the guide wire, including the tight curve greater than 90 degrees, and can be positioned in the left ventricle outflow tract and in the aortic root in one embodiment.

The Examiner further asserts that the specification does not "disclose that the anchor zone is capable of bending, nor to what extent." Office Action, page 3. Applicants respectfully disagree for at least the reasons provided above. In addition, the catheter, which comprises the anchor zone, is described repeatedly as being flexible. See, e.g., paragraphs [0016], [0049], [0053], [0059], [0060] and [0072]. As such, the catheter 18 would be capable of bending. For the foregoing reasons, Applicants respectfully request that the § 112, first paragraph rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 27-29, 31-34, 78-84, and 86-91 were rejected under 35 U.S.C. § 103(a) in the Office Action as being unpatentable over U.S. Patent No. 6,165,183 issued to Kuehn et al. (Kuehn) in view of U.S. Patent No. 4,777,951 to Cribier et al. (Cribier). To establish a prima facie case of obviousness using multiple prior art references, the references must be combinable and must disclose all the claim limitations.

**Kuehn**

Kuehn is directed to a device for heart valve repair in connection with Figures 20-21 that includes a gripper 438 with a plunger 446 that is used to direct leaflets of the valve to gripper arms or "graspers" 440. The graspers 440 are mounted on a grasper tube 441.

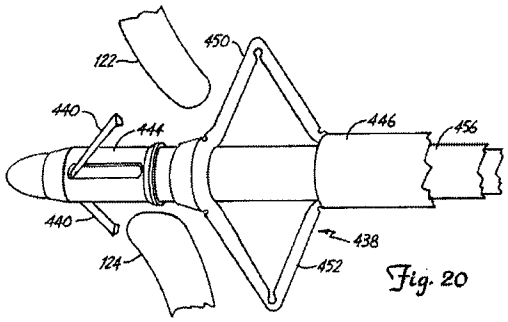

Fig. 20

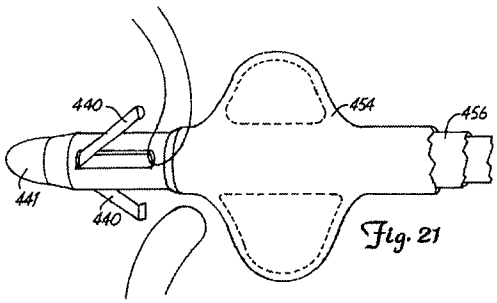

Fig. 21

The Examiner asserts that the grasper tube 441 is an "anchor zone," but concedes that "Kuehn fails to teach wherein the anchor zone is elongate and flexible and configured to bend at least 90 degrees to extend at least into an anatomical region adjoining the heart valve." Office Action, page 4. Applicants disagree that Kuehn discloses any sort of anchor zone at the distal end of the grasper tube 441. In fact, Kuehn teaches away from locating any structure distal of the graspers 440 that would interact with tissue so as to provide any positioning or orienting capabilities.

For example, although the distal end of the grasper tube 441 is not discussed in any detail in Kuehn, it is illustrated as being very short compared to the graspers 440. The graspers 440 are described as being "less than about 10 mm in length." Kuehn at 10:2-3. Thus, Kuehn teaches keeping the section of the gripper 438 distal of the graspers 440 very close to the area through which the valves move, and no longer. While the discussion of the distal end of the grasper tube 441 does not explain why confining the distal end to this space is important, one reason may be that a longer structure would create a substantial risk of entanglement with the chordae tendinae that extend from the valve leaflets through the left ventricle.

Moreover, Kuehn teaches that any structure to position the graspers 440 relative to the valve leaflets should be located proximally of the graspers 440. In particular, the plungers 446, 454 are used to bring the leaflets into engagement with the graspers 440. Kuehn states that "as plunger 446 or 454 reaches a certain position relative to graspers 440 so that graspers 440 are within reach of leaflets 122, 124, shaft 456 is pulled back to retract graspers 440, which clasp leaflets 122, 124 between graspers 440 and grasper tube 441." Kuehn at 9:61-65. Thus, in both variations, Kuehn teaches locating proximally of the graspers 440 a structure that is for bringing the graspers 440 into a position in which the graspers 440 engage the leaflets. Kuehn expresses no reason to add another structure distal of the graspers 440 that would engage the heart or a

vessel to provide an orienting or positioning function because the valve leaflets will be gripped between the proximal plungers 446, 454 and the graspers 440.

In addition, because Kuehn teaches towards using a proximally located mechanism for bringing the graspers 440 into engagement with the valve leaflets, a person of ordinary skill in the art looking to improve on the positioning feature would naturally consider alternative plunger-like features designed to directly engage the valve leaflets from a proximal location, i.e., within the atrium.

Therefore, Kuehn teaches away from an anchor zone, e.g., a distally placed structure that is useful for positioning or orienting the device.

**Cribier**

Cribier is directed to an aortic valvuloplasty catheter instrument 10 for removing calcified deposits on the aortic valve leaflets. The instrument 10 includes a flexible distal tip portion 20 and a dilatation balloon 22 that is inserted through the aortic valve and inflated therein. The tip portion 20 is described as being "very flexible" and being "able to conform to the contours of the ventricle to which it is exposed." Cribier at12:22-24 (emphasis added). As shown in Figure 9, the distal portion 20 of the catheter 10 is curved to rest inside the curved walls of the ventricle, while avoiding or minimizing contact therewith.

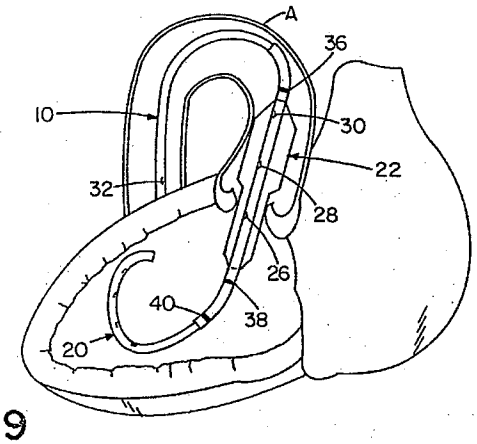


FIG 9

The Examiner asserts that the flexible distal tip portion 20 corresponds to Applicants' anchor zone. See Office Action, page 4. However, the tip portion 20 is not disclosed as having or being capable of this function. Instead the tip portion 20 is for measuring pressure and delivering a contrast agent, while being atraumatic. See Cribier at 11:14-20. To perform these functions, the distal tip 20 would not have to be capable of performing an anchoring function, e.g., enabling

positioning or orienting of the catheter 10. As discussed further below, the tip portion 20 specifically described as being the most flexible part of the catheter 10 and the tip portion would be incapable of acting as an anchor zone. Moreover, it would be inconsistent with the teachings of Cribier to modify it to have the properties of an anchor zone.

For example, the tip portion 20 is required to be soft and flexible to avoid trauma to the heart. Where stiffness is required for positioning or orientation, Cribier teaches to not stiffen the distal portion. For example, Cribier states that the catheter 10 "may include a fourth lumen containing a rod, e.g., of metal or plastic, to provide additional stiffness and torqueability of the catheter over its length to the distal end of the balloon, while not affecting the soft tip." Cribier at 14:40-44. Cribier shows such an embodiment in Figures 15-15c, in which a rod 60 is positioned in a blind lumen, which ends proximal of the distal portion 20. This arrangement would preserve the softness of the distal tip portion 20. See Cribier at 14:53-54. Cribier also more generally states a preference for only making the proximal portion stiff enough to position the balloon 22. See Cribier at 4:21-43. Thus, like Kuehn, Cribier teaches away from providing any feature for positioning or orienting a catheter distal of a procedure zone.

Also, though Cribier discusses the need to be atraumatic, the use of the distal portion 20 for positioning or orienting would result in severe trauma. In particular, movement of the distal curvature of the Cribier device to position or to orient a catheter in the approach taught by Cribier could cause the distal curve to course through the chordae and cause the chordae to be torn. Torn chordae can cause torrential mitral regurgitation and death.

For the reasons set forth above, a combination of the very soft tip portion 20 of Cribier with the very short tip portion of Kuehn's grasper tube 441 would be improper. Additionally, stiffening the very soft tip of Cribier such that it could have a positioning or orienting capability would be contrary to teachings of Cribier. For at least these reasons, the rejection of the claims as obvious is improper.

Also, in contrast to Kuehn and Cribier, Claim 27 has been amended to recite a catheter for accessing the heart and engaging a heart valve, comprising:

> an elongate flexible body, having a proximal end and a distal end;
> an anchor zone on a distal portion of the flexible body the anchor zone being configured to bend at least about 90 degrees to extend at least into an anatomical region adjoining the heart valve and having sufficient rigidity to stabilize the tissue manipulator at the valve; and
> at least one tissue manipulator carried by the flexible body proximally of the anchor zone.

Claim 27 recites limitations not disclosed in either Kuehn or in Cribier. For example, neither Cribier nor Kuehn teach or suggest an anchor zone on a distal portion of the flexible body the anchor zone being configured to bend at least about 90 degrees to extend at least into an anatomical region adjoining the heart valve and having sufficient rigidity to stabilize the tissue manipulator at the valve. For this additional reason, Claim 27 is allowable over Kuehn and Cribier and Applicants respectfully request that the rejection of Claim 27 be withdrawn. Claims 28-34, 78-81 and 92-93 depend from Claim 27 and recite further limitations not recited in Claim 27. Therefore, Claims 28-34, 78-81 and 92-93 are allowable at least for the same reason that Claim 27 is allowable. Applicants respectfully request that the rejection of Claims 28-34, 78-81 and 92-93 be withdrawn.

Similarly, Claim 82 recites a catheter for performing a procedure on the heart, comprising:

> an elongate flexible body, having a proximal end, a distal end and a length sufficient to reach the heart from a femoral vein access;
> at least one tissue manipulator on the elongate, flexible body; and
> an elongate, flexible anchor zone, extending distally of the tissue manipulator;
> wherein the anchor zone is sufficiently flexible and long that it can extend through the mitral valve and into the left ventricular outflow tract to stabilize the catheter while the tissue manipulator is positioned at a leaflet of the mitral valve.

Claim 82 recites limitations not disclosed in either Kuehn or Cribier. For example, neither Kuehn nor Cribier teach or suggest an anchor zone that is sufficiently flexible and long that it can extend through the mitral valve and into the left ventricular outflow tract to stabilize the catheter while the tissue manipulator is positioned at a leaflet of the mitral valve. For this additional reason, Claim 82 is allowable over Kuehn and Cribier and Applicants respectfully request that the rejection of Claim 82 be withdrawn. For at least the reasons stated above, Applicants respectfully request that the rejection of Claim 82 be withdrawn. Also, Claims 83-91 depend from Claim 82 and recite further limitations further distinguishing Kuehn and Cribier. Therefore, Claims 83-91 are allowable at least for the same reason that Claim 82 is allowable. Therefore, Applicants respectfully request that the rejection of these claims be withdrawn.

Claims 30 and 85

Claims 30 and 85 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kuehn and Cribier and further as a matter of design choice. Applicants

respectfully traverse this rejection. Claims 30 and 85 are patentable for at least the reasons described above. Furthermore, these claims recite additional features not taught or supported by Kuehn or Cribier, either alone or in combination.

Cribier teaches that the tip portion should be configured to avoid contact with the ventricle wall to be atraumatic. See Cribier, col. 12 ln. 68 – col. 13 ln 6; Claim 11. Thus, Cribier teaches away from unnecessarily increasing the size of the tip portion 20. In particular, Cribier teaches away from doubling the size of the tip portion 20 from approximately 5 cm to approximately 10 cm, which would substantially increase the amount of contact between the tip portion and the ventricle wall. Doubling the contact area would increase the possibility of trauma, necessarily making the tip portion 20 more traumatic.

Therefore, it would not have been obvious to a person of ordinary skill in the art to increase the size of the distal tip portion to approximately 10 cm. For the foregoing reasons, Applicants respectfully request that the § 103(a) rejection be withdrawn.

New Claims 92-103

Newly added Claims 92-103 recite additional features of Applicants invention and are patentable over the combination of Kuehn and Cribier for at least the reasons discussed above and in view of the additional limitations recited therein. Accordingly, Applicants respectfully request allowance of these new claims.

## CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as

founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicants' attorney, Winston Chu at (949) 721-7622 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: June 18, 2007

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